3.0 510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR Part 807, Section 807.92(c).

Applicant/Submitter: Medtronic Vascular
3576 Unocal Place
Santa Rosa, CA 95403

Tel: 707-525-0111
Fax: 707-566-1245

Contact person: Diana Johnson, Regulatory Affairs Director

Official Contact Person: Maddalena Pinsi, Sr. Regulatory Affairs Specialist
INVATEC, S.p.A.
7, Via Martiri della Libertà
Roncadelle, ITALY 25030.

Tel: 707-591-2656
Fax: 707-566-1245

Email: maddalena.pinsi@medtronic.com

Alternate Contact: Diana Johnson, Regulatory Affairs Director
Medtronic Vascular
3576 Unocal Place
Santa Rosa, CA 95403

Tel: 707-591-2656
Fax: 707-566-1245

Email: diana.j.johnson@medtronic.com

Date Prepared: November 15, 2013

Device Information:

Trade Name:	TOTAL across™
Common Name:	Crossing Support Catheter
Regulation Name:	Percutaneous Catheter
Classification:	Class II
Classification Panel:	Cardiovascular
Regulation Number:	21 CFR 870.1250
Product Code:	DQY

Predicate Devices

- Quick Cross® Extreme Support Catheter (K082561 SE- December 10th, 2008 and K092396 SE- September 4th, 2009)
- Seeker™ Crossing Support Catheter (K103367 SE- December 8th, 2010)

Device Description

The TOTAL across is an over the wire (OTW) single lumen catheter composed of a spiral hypotube which provides a smooth transition from proximal to distal part, a proximal female hub and a distal flexible part with an atraumatic tapered tip.

The distal end of the catheter features a lubricious, hydrophilic coating and 2 radiopaque markers. The TOTAL across is 0.014" (0.36mm) guidewire compatible, and features working lengths of 100cm and 150cm.

Indications for Use

The TOTAL across™ crossing support catheter is intended to guide and support a guidewire during the access of peripheral arteries, allow for wire exchanges, and provide a conduit for the infusion of saline solutions or diagnostic contrast agents.

The indications for use for the TOTAL across are equivalent and covered by the currently cleared predicate devices, Quick Cross® Extreme Support Catheter (hereinafter referred to as "Quick Cross Extreme") and Seeker™ Crossing Support Catheter (hereinafter referred to as "Seeker").

Technological Characteristics

The overall design and the fundamental scientific technology (operating principle and mechanism of action) of the TOTAL across device (hereinafter referred to also as "subject device") are substantially equivalent to the currently cleared predicate devices, Quick Cross Extreme and Seeker.

The subject device has a guidewire compatibility of 0.014", as the Quick Cross Extreme and the Seeker predicate devices (which also have additional platforms having 0.018" and 0.035" guidewire compatibilities).

The TOTAL across has an introducer sheath compatibility of 4F, which is the same as the Quick Cross Extreme and Seeker predicate devices introducer sheath compatibility for the 0.014" platform.

The TOTAL across usable lengths (100cm and 150cm) are within the Quick Cross Extreme and Seeker predicate devices' range (from 65cm to 150cm).

The distal end of the subject device features a lubricious, hydrophilic coating as are the predicate devices Quick Cross Extreme and Seeker.

The subject device features two radiopaque markers per device, while the Quick Cross Extreme predicate device features three radiopaque markers per device. The visibility of the subject device markerbands has been considered satisfactory and comparable to the predicate device's visibility.

Refer to **Section 9.4** and to **Section 10.0** for a detailed description of the subject device and for its comparison to the predicate devices.

Comparative testing was also conducted with the subject device and the predicate devices. The bench test results demonstrated that the subject device met the acceptance criteria and that the predicate devices and the subject device are comparable with respect to the performance characteristics.

Summary of Bench Testing

The TOTAL across was thoroughly tested on the bench to evaluate and verify that it meets the required performance specifications. The bench testing plan was developed with the consideration of the recommendations outlined in the applicable FDA guidance documents and ISO standards. Testing performed on the TOTAL across device included the following:

- Surface Inspection and Device Dimensions
- Device Preparation, Trackability, Flexibility and Kink test
- Introducer Sheath and Guidewire Compatibility
- Catheter Bond Strength
- Tip Pull
- Torque Strength
- Radiopacity
- Coating Evaluation
- Particulate evaluation
- Catheter Body Burst Pressure
- Contrast Media and Saline Solution Flow Rate
- Hub Test according to ISO 594-1:1986 - *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements* and to ISO 594-2:1998 - *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings*
- Crossability

All of the pre-determined acceptance criteria were met and the testing passed.

Summary of Biocompatibility Testing

The TOTAL across is an externally communicating device, which contacts circulating blood for the limited contact duration (<24hours).

Biocompatibility testing was conducted on the finished TOTAL across in accordance with the principles of the ANSI/AAMI/ISO 10993-1:2009 *Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process* as specified in the FDA Blue Book Memorandum #G95-1 *Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'* and in accordance with FDA 21 CFR Part 58: *Good Laboratory Practice for Non clinical Laboratory Studies*, and FDA guidance: *Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters (Sept 2010).*

The biocompatibility testing performed for the TOTAL across device included the following:

- Cytotoxicity Study using the ISO MEM Elution Method
- ISO Guinea Pig Maximization Sensitization Test
- ISO Intracutaneous Study in Rabbits
- ISO Systemic Toxicity Study in Mice
- USP Pyrogen study - Material mediated
- Bacteria Reverse Mutation Study
- ASTM Hemolysis Study
- C3a Complement Activation Assay
- SC5b-9 Complement Activation Assay
- In-vivo Thromboresistance Study in the Dog, Jugular Vein
- ASTM Partial Thromboplastin time

All of the pre-determined acceptance criteria were met and the testing passed.

Assessment of non-clinical performance data for equivalence

Comparative and biocompatibility testing of the TOTAL across were performed in accordance with the relevant FDA guidance, ISO and ASTM standards. Results from these non-clinical testing demonstrates that the TOTAL across met the pre-determined acceptance criteria and results from the comparative testing also demonstrate that the subject device performs comparably to the predicate devices. No new type of safety or effectiveness issues were observed during the testing.

Conclusion

Results from the non-clinical performance testing demonstrate that the TOTAL across is substantially equivalent to the predicate devices in terms of safety, effectiveness and performance.

In conclusion, based on the considerations above, Medtronic believes that the TOTAL across is substantially equivalent to the predicate devices Quick Cross Extreme and Seeker in terms of indications for use, overall design, fundamental scientific technology (operating principle and mechanism of action) and performance characteristics, and that it does not raise new type of questions of safety and effectiveness. Therefore it is suitable for the Traditional 510(k) process.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 26, 2014

Medtronic Vascular
Ms. Diana Johnson
Regulatory Affairs Director
3576 Unocal Place
Santa Rosa, CA 95403

Re: K133539
Trade/Device Name: TOTAL across
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: February 21, 2014
Received: February 24, 2014

Dear Ms. Johnson,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K133539

Device Name

TOTAL across™

Indications for Use *(Describe)*

The TOTAL across™ crossing support catheter is intended to guide and support a guidewire during the access of peripheral arteries, allow for wire exchanges, and provide a conduit for the infusion of saline solutions or diagnostic contrast agents.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Kenneth J. Cavanaugh -S